

Attorney Docket No.: DEX-0230
Inventors: Chen et al.
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REMARKS

Claims 9, 10 and 17 are pending in the instant application. Claims 9, 10 and 17 have been rejected. Claims 9, 10 and 17 have been amended. New claims 18 through 22 have been added. Support for these amendments is provided in the specification at page 11, pages 42-43 and Table 2 of Example 15 beginning at page 141. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 9, 10 and 17 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 9, 10 and 17 have been rejected under 35 U.S.C. § 112, first paragraph. Arguments presented in the last response were not found persuasive as the Examiner suggests that the arguments do not address the enablement issues as to whether or not the polypeptide encoded by SEQ ID NO:15 or the polypeptide of SEQ ID NO:83 are either overexpressed or underexpressed in a specific disease state. The Examiner suggests that Applicants have provided no evidence of record which show that a polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID

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NO:83 are either overexpressed or underexpressed in a specific, diseased tissue compared to a healthy tissue control. The Examiner suggests that in the absence of a direct correlation between the up-regulation of transcription and translation of the polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID NO:83 associated with a specific disease state, one of ordinary skill in the art would be unable to use an antibody that binds the polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID NO:83 in a diagnostic or therapeutic setting.

Applicants respectfully traverse this rejection.

MPEP § 2164 is quite clear; to meet the enablement requirements the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to make and use the claimed invention. Claims of the instant invention are drawn to antibodies, not to use of antibodies as diagnostics or therapeutics as suggested by the Examiner.

Multiple uses for antibodies of the present invention independent of overexpression or underexpression of the target polypeptide in a disease state are taught in the specification. See for example page 66 of the specification wherein use of antibodies to isolate or to identify clones expressing LSG

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polypeptides or to purify LSG polypeptides of the present invention by attachment of the antibody to a solid support for isolation and/or purification by affinity chromatography are described. Also see teachings beginning at page 39 regarding antibodies for use in ELISAs.

Further detailed methodologies for preparation of antibodies are set forth beginning at page 63 of the specification.

Thus, the instant specification teaches one of skill how to make the claimed antibodies and sets forth multiple uses for the claimed antibodies, thus meeting the enablement requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 9, 10 and 17 under 35 U.S.C. § 112, second paragraph

Claims 9, 10 and 17 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner suggests that recitation of "which is differentially

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expressed in cancer cells" in claim 9 is indefinite because it is unclear if the polypeptide encoded by SEQ ID NO:15 (i.e. SEQ ID NO:83) is differentially expressed in cancer cells or if SEQ ID NO:15 is differentially expressed in cancer cells.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 9 to clarify that SEQ ID NO: 15 is a nucleic acid molecule and that the nucleic acid molecule is overexpressed in cancer cells. This amendment is clearly supported by data presented in the application in Table 2 of Example 15 beginning at page 141. Thus, no new matter is added by this amendment.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested in light of this amendment.

III. Rejection of Claims 9, 10 and 17 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 9, 10 and 17 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the specification does not support that recitation that SEQ ID NO:15 is differentially expressed in just any cancer cells.

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Applicants respectfully disagree.

Table 2 in Example 15 at page 141-143 of the instant application provides data for expression of SEQ ID NO:15 in a number of different cancer types. Multiple types of cancers exhibited differential expression of SEQ ID NO:15 in greater than 30% of the samples measured. In particular, bladder, lung, cervical, colon, endometrial, pancreatic, ovarian, prostate, small intestine, stomach and uterine cancer cells all exhibited differential expression in at least 30% of the samples measured. Thus, differential expression of this marker in these cancer samples is actually greater than many useful cancer therapeutics and diagnostics that have been FDA approved and are commercially available. For example, Genentech's product Herceptin® and its diagnostic counterpart, the HercepTest® are very successfully commercially. Yet many publications show the relevant gene, HER-2, is overexpressed in only 30% of breast cancer patients.

Thus, contrary to the Examiner's suggestion, the specification as-filed is supportive of the recitation of SEQ ID NO:15 being differentially expressed in cancer cells.

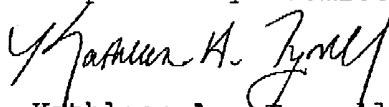
Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

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IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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